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Food and Drug Administration
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Medical Devices; Sunlamp Products Performance Standard; Request for Comments and Information

Thank you for the opportunity to comment on the notice of proposed rulemaking, for Medical Devices; Sunlamp Products Performance Standard. The following comments are submitted for consideration.

Revisions Under Consideration:

1. FDA is considering revising and updating the current sunlamp product performance standard (Sec. 1040.20) and harmonizing it with the International Electrotechnical Committee Standard 335-2-27 for UV and infrared emitting appliances. After consulting with international standards organizations and evaluation of the current scientific knowledge, FDA intends to develop a recommended exposure schedule which part of the development process, FDA intends to review the material on effects of UVA and UVB on skin, the effects of UV exposure on melanoma induction, and the use of photobiological action spectra as a basis for risk assessment in health protection and product safety discussed at the American Society for Photobiology and European Society for Photobiology Joint Workshop on UV and Melanoma, Snowbird, Utah, July 11 through 15, 1998; the International Symposium and Workshop on Measurements of Optical Radiation Hazards, at the National Institute for Standards and Technology, Gaithersburg, MD, September 16 through 18, 1998. The proceedings of these meetings describe current research findings that show a stronger correlation between UV exposure and skin cancer, photoaging, and photoimmunological effects.

Response:

Concur with updating current sunlamp product performance standard (Sec. 1040.20) and

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making it consistent with the International Electrotechnical Committee Standard 335-2-27 for UV and infrared emitting appliances.

2. FDA is considering revising and updating its August 21, 1986, guidance on the determination of the maximum timer interval and recommended exposure schedule for sunlamp products entitled, "Policy on Maximum Timer Interval and Exposure Schedule for Sunlamp Products." FDA is concerned that inadequate attention is being paid to current recommended exposure schedules and that current guidance may allow higher exposures than are necessary to produce and maintain a tan, and it does not incorporate the differences in individual human sensitivity to UV exposure. FDA intends to update this guidance after reviewing and other available information. FDA is further considering incorporation would result in a more comprehensive regulatory standard with all relevant information for compliance in the standard.

Response:

Suggest incorporation of minimum time between exposures become a part of the timer interval and recommended exposure schedule for the sunlamp product. Current recommendation of a minimum of 24 hours between exposures should be a mandatory minimum with a recommended recycle time of 48 hours preferable. Sufficient evidence is available to demonstrate risks outweigh benefit of daily exposures.

3. FDA is considering adding a provision clarifying that manufacturing includes the modification of a sunlamp product, previously certified under Sec. 1010.2, by any person engaged in the business of manufacturing, assembling or modifying sunlamp products if the modification affects any aspect of the product's performance, information or intended function for which Sec. 1040.20 has an applicable requirement. This addition would clarify that sunlamp products are being regulated like other products regulated under Sec. 1010.2. FDA is also considering requiring the manufacturer who performs such modification to recertify and re-identify the product in accordance with the provisions of Secs. 1010.2 and 1010.3. This potential amendment is intended to clarify the responsibilities of firms and individuals who are in the business of installing ultraviolet lamps and new timers with different performance characteristics than the original lamps and timers in previously certified products.

Response:

There is no current method available to validate product modifications with lamps or timers to ensure they are consistent with initial certification of the product. Timers and lamps are routinely replaced and or modified without performance reevaluation and certification. The re-certification requirement needs to include documentation and labeling

to reflect compliance. Labels in use today are usually located where they become illegible rapidly and need to be replaced frequently. Replacement labels do not always represent original certification for lamps and recommended exposure times but are obtained to suit the needs of the provider. Recommend certification labeling be constructed to preclude illegibility and be permanently installed to help ensure compatibility with initial manufacturer timer and lamp certification.

4. FDA is concerned that the current warning label is not read by many tanning salon patrons because it is too long and detailed. Therefore, FDA is considering updating the warning statement required by Sec. 1040.20 (d) (1) (I) to simplify the wording and to highlight the risk of skin cancers. In order to update the warning statements, FDA intends to review and evaluate epidemiological and mechanistic information on UV exposure-related skin cancers, including possibly fatal cutaneous malignant melanoma. In developing its specific proposal for this item, FDA will be reviewing the material presented at the meeting cited previously and other available information.

Response:

The warning label currently required on the tanning unit is usually placed in an inconvenient location for the user to read and also is in small print. The warning is also included with other labeling requirements and gets lost in the maze. Concur with making the warning shorter and more to the point! Recommend this warning label be located independently of other labeling requirements be of larger print and coloring to help highlight the warning. Arizona rules require the same warning statement (larger print size and format) to be posted in the tanning area, and be readily visible to the user. Arizona also requires the user to read the warning statement annually and sign acknowledgement.

5. FDA is considering requiring the reproduction of the text of the warning statement specified in Sec. 1040.20 (d) (1) (I) in catalogs, specification sheets, and brochures pertaining to sunlamp products through catalog mail order or through catalogs on electronic media may not receive information about the associated hazards and risks until the products are delivered to their homes and unpacked.

Response:

Agree! Current advertisements and or promotions do not provide hazard information relative to the use of tanning equipment.

6. To simplify appropriate lamp replacement, FDA is considering the development of a biological efficacy rating scale for ultraviolet lamps intended for use in sunlamp products. Lamp technology continues to evolve, affecting the levels of UV exposure, the spectral characteristics and, therefore, the biological efficacy of ultraviolet suitable for replacement in the product is required on sunlamp products and in the user instructions. Ad new lamps and new lamp manufacturers abandon the lamp designations which are compatible with the product and complaint with the standard. In order to simplify the process, especially for industry and State regulators, FDA is considering a uniform grading/rating system.

Response:

Agree! A less complicated method of verifying lamp compatibility is needed. Consider lamp output values along with lamp plug connections to ensure lamp replacement compatibility. Ex: Bed using lamp output values of X-% UVA-UVB have a unique connector that allows only that output value be installed.

If you have any questions or need further information please call Mr. John Lamb at (602) 255-4845 ext 237.

Sincerely,

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